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TITLE: A Randomized Controlled Trial of In-Home Tele-behavioral Health Care
Utilizing Behavioral Activation for Depression

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14. ABSTRACT The purpose of this study is to establish the safety and clinical efficacy of in-home, web-based psychosocial treatments for depression. This is a necessary step prior to the large scale dissemination of home-based telemental healthcare programs for active duty Service Members, Veterans, and their families. Randomized controlled trials, such as this study, are the gold-standard method of investigating the effects- and comparisons- of specific treatment options. As such, this study has the direct potential to inform and improve current strategies targeting the healthcare needs of our Service Members and Veterans. No current findings to report to date.					
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	5
Reportable Outcomes.....	6
Conclusion.....	6
References.....	6
Appendices.....	6

INTRODUCTION

In-home tele-behavioral health treatments have the potential to address current health needs of Service Members, Veterans, and their families, especially for those that live in rural and underserved areas. The use of in-home, web-based treatment to address the psychological needs of Service Members and Veterans is not yet considered standard of care for the DoD. The safety and clinical efficacy of such treatments must be established before broad dissemination of these treatment programs. This study is a two-group (web-based in-home BA vs. in-person BA) prospective randomized controlled trial. Both groups will be assessed at baseline, mid-treatment (Week 4), post-treatment (Week 8), and at a 3-month follow-up visit. The primary outcome variables are safety and hopelessness. Secondary outcome variables include depression, anxiety, PTSD symptoms, attitudes toward seeking mental health services, quality of life, and health care utilization, as well as treatment satisfaction, adherence, and compliance. A total of 120 participants will be recruited with an anticipated completion rate of 108 participants (54 per treatment group). Participants are Regular Service Members, National Guard Members, Reservists, and Veterans recruited at Madigan Army Medical Center and the Portland VA Medical Center.

BODY

The protocol was reviewed by The Human Research Protection Office (HRPO) and approved on 30 April 2012. The Portland VA site received HRPO approval on 26 September 2012. Currently, both sites are actively enrolling participants. Additionally, continuing review of this protocol, an annual requirement, was completed and approved by the Madigan IRB on 24 October 2012.

Recruitment efforts for the In-Home Depression RCT have been a major focus over the past year (formally beginning 08/2012). To date, 39 potential participants have been referred to the study, 28 of which consented to the study and completed intake interviews. Of those, 23 were eligible for randomization, while 5 failed to meet inclusion criteria. Across both sites, 11 participants are currently in treatment, 2 have withdrawn, 9 have completed the treatment phase and are currently in the follow-up period, and 1 has fully completed the follow-up period.

Recruitment is also underway with the PTSD Pilot Study. There have been 20 participants referred, 14 of which consented to the intake evaluation. Of those, only 6 were eligible for treatment. Prior to starting treatment, 2 of those individuals withdrew their consent. The remaining 4 are currently active in the treatment phase of the study. The focus for both projects continues to be on the recruitment and treatment of eligible participants.

During the period covered by this review, the Madigan Healthcare System IRB approved three specific modifications to this project's research protocol. Two of these modifications were designed to enhance study recruitment via posters and gate banners at JBLM (approval date 10 October 2012) as well as the use of social and electronic media to advertise about the project's goals (approval date 27 November 2012). This modification also increased the number of departments that study staff are able to recruit from, and now include the Dept. of Family Medicine and the Dept. of Ministry and Pastoral Care. The final modification, approved 22

January 2012, added a brief self-report questionnaire to the protocol, designed to assess patient preferences regarding telehealth.

The PTSD Pilot Study protocol was approved by the Madigan Healthcare System Institutional Review board on 14 February 2012. Several modifications have also been made to this protocol during the review period. Specifically, recruitment strategies for this project were widened to include direct referrals from Madigan Behavioral Health Clinics (approval date 18 September 2012). This protocol was also modified to increase the total number of subjects to be recruited from 10 to 30 due to a high rate of ineligible referrals (approval date 18 December 2012) and to broaden the inclusion criteria by removing the upper limit on the primary outcome measure (approval date 28 January 2013). Continuing IRB review, and approval, for this study was completed and approved by the Madigan IRB on 4 February 2013.

During this review period an outcomes assessor was hired at T2/JBLM (start date 09 April 2012). The Clinical Psychologist position was also filled on 04 September 2012. Additionally, the outcomes assessor position at the Portland VA was filled (start date 26 March 2012), as was the Portland VA Research Coordinator position (Start date 23 April 2012).

Challenges

Madigan IRB and HRPO approval proved to be a consistent challenge during the majority of the review period, namely because of delays in the review/approval process for both sites. However, approval has been obtained and both sites are currently enrolling participants.

Initial, referral based recruitment strategies also proved challenging. However, with a full staff, more flexibility in recruitment strategies, and the ongoing development of relationships with providers willing to refer patients, we have been steadily recruiting participants and meeting our quarterly recruitment goals since October 2012.

KEY RESEARCH ACCOMPLISHMENTS

Administrative and Logistical Matters

1. Personnel
 - a. Recruitment, interviewing and hiring an outcomes assessor and clinical psychologist at Madigan was completed, as was the recruitment and hiring of the research coordinator and outcomes assessor at the Portland VA. On October 26th, 2012 one of the studies' postdoctoral fellows completed his fellowship and resigned from the project to accept a position elsewhere. An offer has been extended to- and accepted by- a new post-doctoral fellow, with an anticipated start date of August 2013.
2. Equipment
 - a. All laptops have been configured according to the specifications required for the protocol, and all laptops and webcams are in working order. We currently have a

100% equipment recovery rate from participants who have had equipment checked out to them. All original MOVI/Jabber licenses obtained for this study are still active and being utilized.

3. Materials, supplies and consumables

- a. Materials and required supplies, including study measures, were acquired in anticipation for subject enrollment and data collection. As these supplies are consumed, new supplies are ordered to keep the project running smoothly.

4. Institutional Review Board (IRB)

a. In-Home Depression RCT

- i. Madigan IRB approves protocol modification on 10 October 2012
- ii. Madigan IRB completed Continuing Review on 24 November 2012.
- iii. Madigan IRB approves protocol modification on 27 November 2012.
- iv. Madigan IRB approves protocol modification on 22 January 2013.

b. In-Home PTSD Pilot

- i. Madigan IRB approves protocol modification on 18 September 2012
- ii. Madigan IRB approves protocol modification on 18 December 2012
- iii. Madigan IRB approves protocol modification on 28 January 2013
- iv. Madigan IRB completed Continuing Review on 4 February 2013

REPORTABLE OUTCOMES

None

CONCLUSION

None

REFERENCES

None

APPENDICIES

None